PharmaTher Applauds FDA's Commissioner's National Priority Voucher (CNPV) Selection of Ketamine; Company Highlights Potential Ketamine Opportunity, 505(b)(2) Focus, and Upside from Strategic ANDA Sale

Toronto, Ontario--(Newsfile Corp. - October 17, 2025) - PharmaTher Holdings Ltd. (OTCQB: PHRRF) (CSE: PHRM) (the "Company" or "PharmaTher"), a specialty life sciences company focused on unlocking the pharmaceutical potential of ketamine, today applauds the U.S. Food and Drug Administration's ("FDA") announcement on October 16, 2025 of the first-ever recipients of the new Commissioner's National Priority Voucher ("CNPV") pilot program, which include "*ketamine for domestic manufacturing of a critical drug for general anesthesia."* The pilot elevates ketamine as a national priority.

The CNPV is expected to a catalyst for the ketamine market—and PharmaTher is positioned at the forefront. By prioritizing ketamine, the FDA is signaling to hospitals, GPOs, and public buyers that on-shore, quality-assured supply is a national objective, potentially amplifying demand for reliable U.S. sources. At the same time, the program's team-based review and ~1-2 month decision window reduce regulatory friction for aligned, complete filings, enabling faster conversion of supply into sales. Finally, ecosystem signals—public announcements referencing ketamine API under CNPV and the resolution of multi-year U.S. shortages (February 2018 to August 2025)—point to sustained momentum for ketamine.

Strategic Highlights — What This Means for PharmaTher

- **CNPV fuels PharmaTher's Momentum.** FDA's naming of ketamine as a national-priority anesthesia medicine creates a durable U.S. demand tailwind precisely where PharmaTher can participate economically via its previously announced ANDA sale.

- **Economic participation without heavy spend.** The Company's sterile-injectables partner (the purchaser of the ANDA) brings experienced manufacturing and U.S. regulatory/commercial capabilities. The transaction provides potential payment milestones of up to US$25 million and is *not limited* to US$25 million due to a multi-year profit-sharing component—enabling upside participation without building plants, carrying inventory, or funding a national sales force.

- **Reinforcing PharmaTher's Opportunity.** The previously announced ketamine ANDA sale reduces PharmaTher's execution risk and capital requirements, while preserving significant long-term upside linked to potential U.S. ketamine growth. Importantly, the ANDA sale applies only to *generic ketamine sales in the U.S.*; PharmaTher retains all rights to non-generic applications of ketamine—including new indications, novel formulations and delivery technologies, and its 505(b)(2) programs, which include Parkinson's disease (LID-PD), ALS, CRPS, and the Company's proposed brand, KETARx™.

- **From supply tailwind to pipeline compounding.** The same policy focus that lifts ketamine supply also reinforces the Company's capital-light 505(b)(2) strategy—creating a pathway to additional potential NDAs that can compound value beyond the ANDA economics.

HowCNPV potentially accelerates PharmaTher's capital-light ketamine-based 505(b)(2) strategy

- **Regulatory mechanics favor completeness and speed.** CNPV encourages robust CMC pre-submission and a senior, multidisciplinary review that can deliver ~1-2 month decisions once the

file is complete—aligning with the Company's approach to submit its FDA-aligned CMC, while executing focused clinical "bridges" suitable for 505(b)(2).

- **CMC leverage from PharmaTher's ketamine experience.** The Company's FDA-aligned ketamine CMC know-how (validated methods, specifications, stability programs) from its recent ANDA approval now supports future 505(b)(2) filings.

- **RWE acceptance strengthens PharmaTher's model.** FDA's growing framework for fit-for-purpose Real-World Evidence supports using high-quality RWD/RWE to complement efficient clinical packages for already-approved drugs seeking new indications—further de-risking timelines and cost.

- **CNPV recognition of ketamine signals a constructive FDA outlook for the category.** PharmaTher intends to evaluate potential future CNPV nominations and, where appropriate, pursue other expedited programs (e.g., Fast Track, Breakthrough Therapy) for differentiated ketamine assets.

Partner momentum: a stronger case to commercialize novel ketamine products

CNPV's explicit focus on domestic, reliable ketamine supply strengthens the rationale for pharmaceutical partners to engage in the development and commercialization of novel ketamine products for new indications. Consistent with its October 2, 2025 corporate update, PharmaTher continues active discussions and is positioned first in line to collaborate with U.S.-focused manufacturers and commercial organizations seeking differentiated ketamine programs under the 505(b)(2) pathway.

PharmaTher's Digital Health AI for ketamine tailwind

With ketamine now elevated under CNPV, PharmaTher expects increased data and partnering activity to unlock its ketamine-based pipeline and act as a potential growth driver for its Digital Health AI division, which comprises KetaVault™ (the Company's proprietary ketamine data repository) and the KetAImine™ platform for indication discovery, prioritization, and regulator-aligned program design.

LID-Parkinson's: Phase 3-Ready package under 505(b)(2)

PharmaTher is preparing a Pre-Phase 3 (Type B) FDA package to align on a single, well-controlled registrational trial for LID-PD, consistent with prior Agency feedback. The Company has communicated a U.S. market opportunity of ~US$0.75-$2.2B and continues active partner discussions to support registrational development and commercialization.

"With the FDA's CNPV spotlight for ketamine, our focus continues on the bigger picture and the path ahead," said Fabio Chianelli, Founder & CEO of PharmaTher. "By design, the ANDA sale reduces execution risk and capital burden while preserving substantial, non-dilutive upside through sales milestones and uncapped profit sharing. Coupled with the FDA's CNPV selection for ketamine and the FDA's expanding guidance around RWE, we see a larger, de-risked opportunity in front of PharmaTher. Our capital-light 505(b)(2) approach—grounded in FDA-aligned ketamine CMC know-how—positions us to convert these tailwinds into durable value and pharma partnerships."

For additional information visit www.pharmather.com and download PharmaTher's latest corporate presentation (here).

Note: PharmaTher is not asserting that it—or any partner—is a CNPV recipient. The Company is commenting on the program's explicit inclusion of ketamine, the potential implications for the U.S. market, and for PharmaTher.

About PharmaTher

PharmaTher Holdings Ltd. (OTCQB: PHRRF) (CSE: PHRM) is a specialty life sciences company focused on unlocking the pharmaceutical potential of ketamine. For more information, visit PharmaTher.com.

For more information about PharmaTher, please contact:

Fabio Chianelli
Chief Executive Officer
PharmaTher Holdings Ltd.
Tel: 1-888-846-3171
Email: info@pharmather.com
Website: www.pharmather.com

Neither the Canadian Securities Exchange nor its Regulation Services Provider have reviewed or accept responsibility for the adequacy or accuracy of this release.

Cautionary and Forward-Looking Statements

Forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially. There can be no assurance that the Company will proceed with the clinical development and that the FDA will support any potential request for an expedited path to approval. These risks include, among others, the commercial performance of the ANDA product, FDA acceptance of the regulatory plan, clinical development, CMC package, regulatory approvals, market acceptance and opportunities, competition, market size, the Company programs being partnered. Readers are cautioned not to place undue reliance on forward-looking statements. PharmaTher disclaims any obligation to update or revise forward-looking statements except as required by law. In addition, this press release contains cautionary and forward looking statements and information within the meaning of applicable Canadian securities legislation. These relate to future events or future performance. The use of any of the words "aim", "anticipate", "before", "believe", "closer", "confident", "could", "eligible", "enable", "ensure", "estimated", "expect", "intend", "lead", "leverage", "makes", "may", "mitigate", "plan", "position", "potential", "prior", "promise", "projected", "proposed", "provide", "purpose", "ready", "significant", "strong", "toward", "will", "would", and similar expressions and statements relating to matters that are not historical facts are intended to identify forward-looking information and are based on PharmaTher Holdings Ltd. (the "Company") current belief or assumptions as to the outcome and timing of such future events. Forward-looking information is based on reasonable assumptions that have been made by the Company at the date of the information and is subject to known and unknown risks, uncertainties, and other factors that may cause actual results or events to differ materially from those anticipated in the forward-looking information. Given these risks, uncertainties and assumptions, you should not unduly rely on these forward-looking statements. The forward-looking information contained in this press release is made as of the date hereof, and Company is not obligated to update or revise any forward-looking information, whether as a result of newinformation, future events or otherwise, except as required by applicable securities laws. The foregoing statements expressly qualify any forward-looking information contained herein. Factors that could cause actual results to differ materially from those anticipated in these forward-looking statements are described under the caption "Risk Factors" in the Company's management's discussion and analysis for the year ended May 31, 2025, dated September 26, 2025, which is available on the Company's profile at www.sedarplus.ca.

This news release does not constitute an offer to sell or the solicitation of an offer to buy, and shall not constitute an offer, solicitation or sale in any state, province, territory or jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state, province, territory or jurisdiction.

To view the source version of this press release, please visit
https://www.newsfilecorp.com/release/270847